REMARKS/ARGUMENTS

Claims 1-23 remain unchanged.

Reconsideration of the claims rejection is requested and allowance of all claims at an early date is solicited.

Election/Restrictions

The withdrawal of the species election requirement is acknowledged. Applicant thanks the Examiner for the reconsideration and withdrawal of the restriction requirement of 7/22/2008.

35 USC §103 Rejection

Independent claims 1 and 23 were rejected under 35 USC §103(a) as being unpatentable over Sherman et al (US6419958) in view of Oosterbaan et al (US 6696496) and further in view of Mulye (US 2002/0155156). Claims 2-22 depend upon claim 1 and were also rejected under 35 USC §103(a) as being unpatentable over Sherman et al (US6419958) in view of Oosterbaan et al (US 6696496) and further in view of Mulye (US 2002/0155156).

The rejection of claims 1-23 is respectfully traversed for the following reasons.
Neither Sherman et al, nor Oosterbaan et al, not Mulye teach or suggest developing extended release tablets of Venlafaxine HCL, as claimed in claim 1.

1. It was acknowledged in the office action of 3/2/09 that "Sherman does not teach the controlled release formulation of Venlafaxine HCl in the form of mini-tablets" (page 5, lines 9-10 of the office action of 3/2/09). Contrary to that Sherman et al teaches formulating Venlafaxine HCl in the form of spheroids. As we will explain below Sherman et al chose spheroids because their "numerous attempts to produce extended release tablets proved to be fruitless" (see WO1999/22724, page 2, lines 20-223)

At this point, we would like to introduce in the proceedings document WO 1999/22724 (also of Sherman et al) which discloses a hard gelatin capsule containing extended release spheroids which comprise a core of Venlafaxine HCl as well as a coating layer over the spheroid cores. The spheroids of WO '724 are prepared by extrusion and spheronization of mixture of Venlafaxine HCl and excipients (see WO '724 page 6, lines 9 to 12; page 7, lines 14 to 17; page 8, lines 6 to 11).

In WO '724 and in EP0797991 (also of Sherman et al; and which is cited in WO '724, owned by the innovator of the extended release capsule of Venlafaxine HCl and marketed product under the brand name EFFEXOR XR ©), it is also acknowledged that Venlafaxine HCl is difficult to be formulated in extended release tablets due to its **high water solubility** (572mg/ml) and several attempts to produce extended release tablets have failed, see WO '724 page 2, lines 15 to 25.

Thus, Sherman et al clearly teaches that coated spheroids were used because it was not possible to produce extended release tablets. This teaching does not suggest or motivate a skilled person in the art to develop extended release tablets of Venlafaxine HCL. Therefore, we conclude that Sherman et al not only does not teach developing extended release tablets of Venlafaxine HCL, but actually discourages i.e., teaches away from developing extended release tablets of Venlafaxine HCL.

2. Oosterbaan et al also acknowledges the difficulties of formulating extended release tablets of Venlafaxine HCL (see col. 2, lines 15- 37 and 44 – 54). Oosterbaan et al addresses the problem of high water solubility of Venlafaxine HCL and the difficulty of formulating tablets of the highly water soluble Venlafaxine HCL by using "the discovery of low water-soluble Venlafaxine salts. Unlike Venlafaxine HCL, the low water-soluble salts are more easily formulated into extended release formulations including hydrogel tablets" (see col. 2, lines 56-65). Therefore, the subject-matter of US '496 is limited only to Venlafaxine salts which have lower water-solubility relative to Venlafaxine HCL and preferably less than 380 mg/ml (see col. 2, lines 57 – 65; col. 3, lines 39 – 50; col. 4,

lines 5 - 10). Venlafaxine HCL has been explicitly excluded from the subject-matter of US '496.

In other words, Oosterbaan although it teaches formulating tablets Venlafaxine salts it admits that it is difficult to formulate extended release tablets of Venlafaxine HCL and therefore Oosterbaan indirectly teaches away from developing extended release tablets of Venlafaxine HCL. Accordingly, the combination of Sherman et al with Oosterbaan et al not only does not teach developing extended release tablets of Venlafaxine HCL, but actually teaches away from developing extended release tablets of Venlafaxine HCL.

3. Mulye (US 2002/0155156) teaches coating a solid dosage form of a medicament in order to produce controlled release of the active ingredient. As it can be seen from figures 1 to 3 of US application '156 the release of the active agents (Verapamil tablet, Glipizide tablet, Tramadol) is controlled by the coating layer. However, nowhere, in the entire application Venlafaxine HCL is disclosed as being an active agent the release of which can be controlled by the disclosed coating. Furthermore, there is no suggestion to use the disclosed coating in order to avoid the initial "burst" release phenomenon of high water soluble active agents. In other words, Mulye also does not teach developing extended release tablets of Venlafaxine HCL by coating them with the disclosed coating and nowhere in the entire specification there is motivation or suggestion to use the disclosed coating in order to produce extended release tablets of Venlafaxine HCL.

The functional coating layer or film of the present application does not by itself exhibit any sustained release properties, however the coating allows the release of the active ingredient from the core in the stomach after administration and its function is only to limit the surface of the core initially available for drug release and thus to reduce the initial rapid release in order to avoid the "burst" effect. The sustained release of the drug from the mini-tablets of the present invention is achieved by the core of the mini-tablets, namely the matrix formed with Venlafaxine HCL

Accordingly, the combination of Mulye with Sherman et al and/or with Oosterbaan et al also does not teach or provide suggestions for developing extended release tablets of Venlafaxine HCL.

Based on the above mentioned reasons it is concluded that neither Sherman et al nor Oosterbaan et al nor Mulye or their combination teach or suggest developing extended release tablets of Venlafaxine HCL, as claimed in claim 1. Accordingly, it is concluded that claim 1 is patentable over Sherman et al, Oosterbaan et al, Mulye alone or in combination.

Claims 2-22 depend directly or indirectly upon claim 1 and since claim 1 is patentable over Sherman et al, Oosterbaan et al, Mulye alone or in combination, they should also be patentable over Sherman et al, Oosterbaan et al, Mulye alone or in combination.

Claim 23 is a method claim corresponding to compound claim 1 and since claim 1 is patentable over Sherman et al, Oosterbaan et al, Mulye alone or in combination, claim 23 should also be patentable over Sherman et al, Oosterbaan et al, Mulye alone or in combination.

It is believed that all of the pending claims have been addressed in this paper. Failure to address a specific rejection, issue or comment, does not signify agreement with or concession of that rejection, issue or comment. Nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

In view of the above, it is submitted that claims 1-23 are in condition for allowance. Reconsideration of the claims rejection is requested and allowance of all claims at an early date is solicited.

If this response is found to be incomplete, or if a telephone conference would otherwise be helpful, please call the undersigned at 781-235-4407

Respectfully submitted,

/Aliki K. Collins, Reg. No: 43,558/

Aliki K. Collins, Ph.D.
Reg. No. 43,558

AKC Patents, 215 Grove Street, Newton, MA 02466
TEL: 781-235-4407, FAX: 781-235-4409

Certificate of Mailing
Date of Deposit 6/1/2009
Name: Aliki K. Collins, Ph.D. Signature /Aliki K. Collins, Reg. No: 43,558/
I hereby certify under 37 CFR 1.10 that this correspondence is being electronically at the USPTO on the date indicated above and is addressed to the Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450